

1 Claims

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3 1. A cardiac valve prosthesis comprising:

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5 a frame and at least two flexible leaflets;

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7 wherein the frame comprises an annular portion
8 which, in use, is disposed substantially
9 perpendicular to the blood flow, the frame
10 having first and second ends, one of the ends
11 defining at least two scalloped edge portions
12 separated and defined by at least two posts,
13 each leaflet being attached to the frame along
14 a scalloped edge portion and being movable
15 between an open and a closed position,

16

17 each of the at least two leaflets having a
18 blood inlet side, a blood outlet side and at
19 least one free edge, the at least two leaflets
20 being in a closed position when fluid pressure
21 is applied to the outlet side such that the at
22 least one free edge of a first leaflet is urged
23 towards the at least one free edge of a second
24 or further leaflet, and the at least two
25 leaflets being in an open position when fluid
26 pressure is applied to the blood inlet side of
27 the at least two leaflets such that the at
28 least one free edge of the first leaflet is
29 urged away from the at least one free edge of
30 the second or further leaflet;

31

1 wherein in a first plane perpendicular to the
2 blood flow axis the length of each leaflet in a
3 circumferential direction (XY) between the
4 posts at any position along the longitudinal
5 axis (Z) of a post is defined by a parabolic
6 function.

7
8
9 2. The cardiac valve prosthesis as claimed in
10 claim 1 wherein the parabolic function defining
11 the length of a leaflet in the circumferential
12 direction (XY) between the posts at any
13 position along the longitudinal axis (Z) of a
14 post is defined by

15
16
$$Y_z = \left(\frac{4R}{L_z^2} \right) x \cdot (L_z - x)$$

17
18 Wherein Y_z = Y offset at a particular co-ordinate X
19 and Z

20 R = parabolic maximum

21 L_z = straight line distance between a
22 first post and a second post of the frame
23 at a height Z

24 x = distance from origin of post towards
25 another post

26
27 and the length of the parabola defined by
28 the above is determined by

29

1 Length = $\int_0^1 \sqrt{1 + \left(\frac{dy}{dx}\right)^2} dx$

2

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4 3. The cardiac valve prosthesis as claimed in any
5 preceding claim comprising three leaflets.

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7 4. The cardiac valve prosthesis as claimed in any
8 preceding claim wherein the frame is a
9 collapsible stent.

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11 5. The cardiac valve prosthesis as claimed in any
12 preceding claim wherein at least one leaflet is
13 configured to increase the length of the free
14 edge of the leaflet relative to the length of
15 the leaflet in the XY direction.

16

17 6. The cardiac valve prosthesis as claimed in
18 claim 5 wherein the free edge of the leaflet is
19 configured such that in a longitudinal
20 direction (Z) perpendicular to the XY direction
21 the free edge of the leaflet is parabolic.

22

23 7. A valve leaflet for use in the valve according
24 to any one of claims 1 to 6, wherein said
25 leaflet has first and second lateral edges each
26 for attachment to a corresponding post, wherein
27 the length of the leaflet in a circumferential
28 direction (XY) between the lateral edges at any
29 position along the lateral edge for attachment
30 to the post is defined by a parabolic function.

1 8. A valve leaflet as claimed in claim 7 wherein
2 the parabolic function is defined by
3

$$4 \quad Y_z = \left(\frac{4R}{L_z^2} \right) x \cdot (L_z - x)$$

5

6 Wherein Y_z = Y offset at a particular co-ordinate X
7 and Z

8 R = parabolic maximum

9 L_z = straight line distance between a

10 first lateral edge for attachment to a

11 corresponding post and a second lateral

12 edge for attachment to second

13 corresponding post at a height Z

14 x = distance from origin of first

15 corresponding post towards second

16 corresponding post

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18 and the length of the parabola defined by

19 the above is determined by
20

$$21 \quad \text{Length} = \int_0^L \sqrt{1 + \left(\frac{dy}{dx} \right)^2} dx$$

22

23

24 9. A method of manufacturing a cardiac valve
25 prosthesis wherein the method comprises;
26

27 (a) providing a forming element having at least
28 two leaflet-forming surfaces wherein the
29 forming surfaces are such that the length in

- 1 the circumferential direction (XY) of the
2 leaflet-forming surface is defined by a
3 parabolic function,
4 (b) engaging the forming element with a frame,
5 (c) applying a coating over the frame and the
6 engaged forming element, the coating binding to
7 the frame, the coating over the leaflet-forming
8 surfaces forming at least two flexible
9 leaflets, the at least two flexible leaflets
10 having a length in the circumferential
11 direction (XY) defined by a parabolic function
12 and a surface contour such that, in use, when
13 the first leaflet is in the neutral position an
14 intersection of the first leaflet with at least
15 one plane perpendicular to the blood flow axis
16 forms a wave,
17 (d) disengaging the frame from the forming
18 element.
19
- 20 10. The method as claimed in claim 9 wherein the
21 valve is a valve according any of claims 1 to
22 6.
23
- 24 11. The method as claimed in claims 9 or 10 wherein
25 the forming element has three leaflet-forming
26 surfaces.
27
- 28 12. The method as claimed in any one of claims 9 to
29 11 further comprising the step of shaping a
30 free edge of a leaflet.
31

- 1 13. The method according to claim 12 wherein said
2 free edge of the leaflet is shaped to a
3 parabola in a longitudinal direction (Z)
4 perpendicular to the XY direction.
5
- 6 14. A method of designing a cardiac valve
7 prosthesis of any of claims 1 to 6 comprising
8 the steps,
9
- 10 a) providing a model of a heart valve
11 comprising a frame and at least two flexible
12 leaflets,
13
- 14 b) generating loads experienced by at least one
15 cardiac valve leaflet in use and applying these
16 to the model,
17
- 18 c) determining the stress distribution of the
19 leaflet,
20
- 21 d) changing the circumferential length of the
22 leaflet in XY for any position in Z,
23
- 24 e) determining the new stress distribution of
25 the leaflet,
26
- 27 f) repeating steps D and E to minimise local
28 stress concentrations in the leaflet.
29
- 30 15. A method as claimed in claim 14 which further
31 includes the step of adjusting the model to
32 account for factors which influence the stress

1 distribution of the leaflet during the cycling
2 of the cardiac valve between an open and closed
3 position.

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5 16. A cardiac valve prosthesis as substantially
6 herein before described with reference to one
7 or more figures 2a, 3, 4a, 4b, 4c, 4d, 5a, 6,
8 7a, and 7b of the accompanying drawings.

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10 17. A leaflet as substantially herein before
11 described with reference to one or more figures
12 9a, 9b, 9c, 9d, 10 of the accompanying
13 drawings.

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